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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,631	10/23/2001	Shanta Modak	A34446 - 070050.1571	4038

7590 11/14/2003

BAKER BOTTS L.L.P.  
44TH FLOOR  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112-0228

EXAMINER
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CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/14/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/047,631

Applicant(s)

MODAK ET AL.

Examiner

Theodore J. Criares

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 9-20 and 30-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 21-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **CLAIMS 1-40 ARE PRESENTED FOR EXAMINATION**

Applicants' PTO-1449 form filed January 8, 2003 (paper #4) is missing from the file. It is requested that a duplicate be forwarded to the office for execution by the Examiner. The references are present but the Form is missing.

### **DETAILED ACTION**

Applicant's election with traverse of the species of Group I, claims 1-8 21-29 and 40 in Paper No.8 is acknowledged.

The traversal is on the ground(s) that all the claims require the active agent octoxyglycerine. This is not found persuasive because the other claimed species would require a separate search and have acquired a separate status in the pharmaceutical art. Further, as set forth herein after applicants' invention relates to a **synergistic composition** which requires different considerations as to patentability for each combination. Claims 40 has not been examined since it includes a species which is not within the elected group, i.e., phenoxyethanol.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-20 and 30-40 are withdrawn from consideration.

### **Objection**

Claim 4 is objected to since it is redundant to claim 3.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-8 and 21-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for synergistic compositions, does not reasonably provide enablement for claims to generic compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Review of the applicants' examples establishes a synergistic composition of octoxyglycerin, chlorhexidine digluconate and benzalkonium chloride. There is a lack of data to support the generic claims 1-8 and 21-29.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-8 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rizvi et al. (6,613,312) in view of Jampani et al. (6,022,551) and Johnson (6,420,431)

Applicants' invention relates to a synergistic composition of skin friendly antimicrobial agents.

Rizvi et al. teach at column 4, lines 55-67 that quarternary ammonium and octoxyglycerin are well known antimicrobial compounds. The difference between applicants' claims and this reference is that the reference fails to teach the use of biquinadine antimicrobial agent. However, the skilled artisan would have been motivated to incorporate chlohexadine, a biguinadine compound into the antimicrobial composition since Jampani et al. disclose and teach at column 2, line 14 to column 2, line that chlorhexidine gluconate (see column 2, lines 39-49) and an alcohol (see column 1, line 65 to column 2, line 10) is an effective antimicrobial composition and "skin friendly" since it is used in deodorant.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960).

As this court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in the prior art. "

In this application it would have been prima facie obvious to combine the antimicrobial compositions of Rizvi et al , which teach the composition of a quaternary

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ammonium compound and octoxyglycein with an antimicrobial composition of chlohexidine in alcohol.

Therefore claims 1-8 and 21-29 are deemed obviated under 35 USC 103(a) in view of the above.

The amounts of alcohol and quaternary ammonium agents in the composition as claimed in claims 25-28 are intrinsic in the teachings of Jampani et al. at column 1, line 65 to column 2, line 10.

The addition of a zinc agent to the composition as claimed in claim 29 is also intrinsic in the teachings of Modak et al. which teaches at column 2, lines 8-26 that the addition of zinc silicates prevents skin irritation and is therefore "skin friendly".

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

None of the claims are allowed.

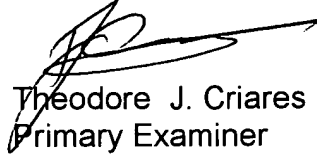
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 305-1877. The fax phone

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number for the organization where this application or proceeding is assigned is 703-746-6897.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.



Theodore J. Criares  
Primary Examiner  
Art Unit 1617

tjc  
11/9/03